Facility Licensing and Investigations Section of the Department of Public Health Approved 5/28/19 SHN

Provider ID No.: 070019	Building:01-Entire Campus East & West	Survey Commenced on May 9, 2019	
Name of Provider: Milford Hospital		Address: 300 Seaside Avenue Milford, CT 06460	
Violation of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut		Plan of Correction	Completion Date

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) (B) and/or (4) (A) and/or (d) Medical records (3) and/or (e) Nursing Services (1) and/or (i) General (6). _		
1. Based on medical record reviews, review of facility policy, review of facility documentation, and interview, for one of three patients' reviewed for surgical services (Patient #8), the facility failed to ensure the correct gamma implant was utilized during hip surgery. The finding includes: a. Patient (P) #8 had open reduction internal fixation of the left hip on 11/12/18 by Medical Doctor (MD) #2 post fall. Review of the intraoperative implant record dated 11/12/18 identified that a left gamma nail was implanted, however, the immediate operative report labels for the implants identified, in part that a right gamma nail (instead of a left) was implanted during P #8's left hip surgery. P #8 was discharged on 11/17/18 to a long term care facility, fell and was readmitted to the facility on 11/19/18 with a left distal femur fracture. P #8 was transferred to Hospital #2 on 11/21/18 following stabilization due to the need for the assistance of a trauma surgeon during surgery. Facility documentation indicated that Hospital #2 reported to the facility that on 1/10/1 8, aright sided gamma nail was removed from P #8's left femur during the left hip surgery that was conducted on 11/12/18. Interviews with MD #2, Surgical Technician (ST) #1 and Registered Nurse (RN) #1 on 5/7/19 at 10:27 AM, 11:16 AM and 8:30 AM respectively, noted that the case was difficult and although the Sales Representative read off the gamma implant details and opened the sterile implant, the implant box with the written details was not visualized by MD #2, ST#1 and/or RN #1. Further interview with MD #2 on 5/7/19 at 10:27 AM noted that although P #8 had the wrong side nail inserted during the surgery on 11/12/18, P #8's left femur accommodated the right gamma nail and this did not cause P #8's second fall/injury. Review of the facility Sales Representative policies dated 3/2013 and 6/2017 identified that under no circumstances may the Sales Representative participate in a procedure by handling, opening or dispensing sterile supplies and/or equipment. Subsequent to the event, the facility submitted a CAP (corrective action plan) to include policy revision requiring a second time out for implants, staff education and monitoring. The facility was found to be compliant with the CAP as submitted.	See attachment #1	See attachment #1

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3. Based on clinical record review, interview and review of facility policy for one of three patients reviewed for patient education (Patient #5) the facility failed to ensure that ostomy education was provided to the patient. The finding included: a. Patient #5 was admitted to the hospital on 7/27/17 with diagnoses that included acute diverticulitis. Review of a computerized tomography (CT) scan report dated 7/27/17 identified a peri-sigmoidal abscess and IV antibiotics were initiated and, on 7/28/17 the patient underwent an insertion of a percutaneous pelvic abscess drain. Review of the patient's clinical record for the period of 7/28/17 to 7/31/17 identified that, the patient demonstrated clinical improvement with a reduced white blood count however review of a nurse's note dated 8/1/17 identified that the patient had increased abdominal cramping with nausea. Review of an abdominal and pelvic CT scan report dated 8/1/17 identified that patient had a new abscess and severe active diverticulitis and surgery was scheduled for 8/2/17. Review of the patient's operative report dated 8/2/17 identified that the patient underwent a Hartmann Procedure, sigmoid colectomy with end colostomy. Review of the patient's care plan dated 8/2/17 identified that the patient had a colostomy to the left lower abdomen with a drainable collection device. Interventions related to the colostomy included bowel diversion assessments and skin assessments related to the patient's colostomy however failed to address patient education related to stoma care and/or care of the collection device. The facility failed to ensure that a comprehensive care plan was in place to address the patient's educational needs related to the care of his/her colostomy. Additionally, a review of the patient's clinical record for the period of 8/2/17 to 8/9/17 failed to identify documentation that the patient was provided information and/or education of ostomy care. Interview with the Nursing Director on 5/9/19 at 11:00 AM identified that it was expected that the patient would be provided ostomy education after the procedure and prior to discharge and this education would be documented in the patient's clinical record. Review of the Patient Education Policy identified, in part, that patients are assessed for learning needs. All disciplines are involved in identifying and providing the educational needs of the patient and all disciplines will document the education provided, to whom the education was given and whether or not follow up is needed. Additionally, the Nursing Director identified that when this issue was identified in September 2017, a revised wound and ostomy policy was put into place to ensure that the wound/ostomy nurse consult is required for any patient with a new colostomy.	See attachment #1	See attachment #1

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b. Review of a physician's order dated 8/3/17 at 11:16 AM directed to change the patient's JP dressing site as needed and daily with gauze packing. Review of the patient's clinical record for the period of 8/3/17 to 8/8/17 identified that the patient's JP drain site was monitored and the dressing was changed on 8/6/17 at 7:00 PM however the record failed to identify that the gauze packing was changed daily in accordance with the physician's orders. Review of Patient #5's electronic medical record and interview with the Nursing Director on 5/8/19 identified that the physicians' orders during the period of 8/3/17 to 8/4/17 were changed without discontinuing the previous orders and the treatment orders may not have been clear. The Director identified that this likely resulted in the patient's dressing changes being done PRN (as needed) at times, rather than daily and/or twice daily. The Director identified that, although there was no specific policy regarding the clarification of treatment orders, as a standard of practice when orders are not clear, nursing staff was expected to clarify the order with the prescribing physician. The Director identified that when this issue was identified in September 2017, a revised wound and ostomy policy was put into place to ensure that the wound/ostomy nurse consult is required.			

Director's or Provider/Supplier Representative's Signature	Title	Date
Ellen M. Solomon, CPHQ Ellen M. Solomon	Interim Director, Quality Management	May 24, 2019

Milford Hospital – 070019 May 24, 2019
DPH Violation Letter May 17, 2019 / Dates of Visit May 6-9, 2019

DPH Violation #	Provider Plan of Correction	Completion Date
1.	The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) (B) and/or (4) (A) and/or (d) Medical records (3) and/or (e) Nursing Services (1) and/or (i) General (6), **Changes implemented to prevent a recurrence:** • The Time Out Verification Policy (T-06-NRS-ORS) has been revised to demonstrate the need for the OR team to perform a second time out. Specifically, prior to implantation of any device, the OR team including the surgeon, will perform a second time out. This second time out will verify the implant is the correct one for the patient. The verification process includes: brand/manufacturer name, expiration date, name of implant, laterality, if appropriate, type of fixation and implant size. This will be documented in the surgical record. • The Sales Representatives in the Operating Room Policy (S-15-NRS-ORS) has been revised to prohibit sales representatives from opening and dispensing sterile supplies/equipment (including implants/prosthetics) onto the sterile field. • The Sales Representatives-Access to Hospital Policy (S-40-EXE) has been revised to prohibit sales representatives from opening and dispensing sterile supplies/equipment (including Implants/prosthetics) onto the sterile field. • OR nursing staff and credentialed medical staff were educated on the revised policies. • Audits were performed on the newly implemented second time out process documentation. These audits were conducted on all surgical cases with implants for one month. Further audits will be conducted on 10 cases per month for 3 months. • Policies revised as 01/2019. Education provided to OR staff on policy revisions 01/23/19 and 2/1/19. • Education provided for surgical medical staff on policy revisions 2/7/19-2/15/19. **Monitoring plan:** • Audits were performed on the newly implemented second time out process documentation. These audits were conducted on all surgical cases with implants for one month. Further audits were conducted on 10 cases per month for 3 months. **Responsible:** Chair of Surgery Perioperative Nurse Manager	01/31/2019 01/31/2019 01/31/2019 2/15/2019 5/31/2019 2/1/2019 2/15/2019 5/31/2019

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2.	The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) (B) and/or (4) (A) and/or (i) General (6). **Changes implemented to prevent a recurrence:** • The Chief Medical Officer will provide counseling with MD #6 on the rules and regulations of the Organized Medical Staff regarding the responsibility for the timely and continuous medical care of each patient. Counseling will include the findings of the violation. • This violation will be presented at Med/Exec Committee by the chief medical officer. **Monitoring plan:** • MD # 6 will be monitored for trends. **Responsible:** Chief Medical Officer	5/31/2019 S/28/2019 Ongoing
3.	The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical records (3) and/or (e) Nursing Services (1). **Changes implemented to prevent a recurrence:** • A revised Skin-Wound and Ostomy Consult Policy (W-010-NRS) was implemented in 9/2017 when it was identified there was a need for a policy surrounding ostomy education to comply with the assessment of patient's learning needs. The policy was put in place to ensure the wound/ostomy nurse consult is required for any patient with a new colostomy. • The Wound/Ostomy nurse will document in the medical record post-surgical ostomy care and education. **Monitoring plan:** • A retrospective review of 5 or all new ostomy patient records for documentation of ostomy education for 3 months. **Responsible:** Executive Director of Patient Care Operations	9/30/2017 S/31/2019

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STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Renée D. Coleman-Mitchell, MPH
Commissioner

Ned Lamont
Governor

Susan Bysiewicz
Lt. Governor

Healthcare Quality And Safety Branch

May 17, 2019

Mr. Mark Toney Presidnet/CEO
Milford Hospital, Inc
300 Seaside Avenue
Milford, CT 06460

Dear Mr. Toney:

Unannounced visits were made to Milford Hospital, Inc on May 6, 7, 8, and 9, 2019 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigations..

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice.

The plan of correction is to be submitted to the Department by May 28, 2019.

The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;

(2) the date each such corrective measure or change by the institution is effective;

(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and

(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

You may wish to dispute the violations and you may be provided with the opportunity to be heard.. If the violations are not responded to by May 28, 2019 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

DATE(S) OF VISIT: May 6, 7, 8, and 9, 2019

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

An telephone conference has been scheduled for June 6, 2019 at 10:00 AM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting.

Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Susan H. Newton, RN, SNC
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:bh:

Complaint #CT22818, CT22104, CT21967, CT24370, CT24082, CT24010, CT23009, CT25341, CT24788, CT22827

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THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

assessment records for the period of 8/5/17 at 9:00 AM to 8/6/17 at 11:00 PM identified that the patient's dressing was dry and intact, however the medical record failed to identify the dressing was changed twice daily as ordered. Review of a nurse's note dated 8/8/17 at 11:56 AM identified that the patient's abdominal dressing was changed. A review of the patient's clinical record for the period of 8/8/17 at 1:00 PM to 8/9/17 at 9:00 AM identified that the patient's dressing was dry and intact however, the note failed to identify that the dressing had been changed twice daily, as ordered.

b. Review of a physician's order dated 8/3/17 at 11:16 AM directed to change the patient's JP dressing site as needed and daily with gauze packing. Review of the patient's clinical record for the period of 8/3/17 to 8/8/17 identified that the patient's JP drain site was monitored and the dressing was changed on 8/6/17 at 7:00 PM however the record failed to identify that the gauze packing was changed daily in accordance with the physician's orders. Review of Patient #5's electronic medical record and interview with the Nursing Director on 5/8/19 identified that the physicians' orders during the period of 8/3/17 to 8/4/17 were changed without discontinuing the previous orders and the treatment orders may not have been clear. The Director identified that this likely resulted in the patient's dressing changes being done PRN (as needed) at times, rather than daily and/or twice daily. The Director identified that, although there was no specific policy regarding the clarification of treatment orders, as a standard of practice when orders are not clear, nursing staff was expected to clarify the order with the prescribing physician. The Director identified that when this issue was identified in September 2017, a revised wound and ostomy policy was put into place to ensure that the wound/ostomy nurse consult is required.